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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/756,411	01/08/01	LORI	F NIH061.1CP1C

020995 HM12/0613  
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EXAMINER	
CRANE, L	
ART UNIT	PAPER NUMBER

1623 9  
DATE MAILED: 06/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>09/756,411</b>	Applicant(s) <b>Lori et al.</b>	
	Examiner <b>L. E. Crane</b>	Group Art Unit <b>1623</b>	

**- THE MAILING DATE of this communication appears on the cover sheet beneath correspondence address -**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be filed after six months from the date of this communication.
- If the prior for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 USC §133).

### Status

- ☒ Responsive to communication(s) filed on 01/08/01 (Amdt A & IDS)-.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claims 1-20 are pending in the application. Claim(s) 1 have been cancelled.  
Of the above claim(s) 1 is/are withdrawn from consideration.
- ☐ Claim(s) 1 is/are allowed.
- ☐ Claims 1-20 are rejected.
- ☐ Claim(s) 1 is/are objected to.
- ☐ Claim(s) 1 are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☒ The drawings, filed on 01/08/01 are ☒ approved ☐ disapproved.
- ☐ The drawing(s) filed on 1 is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119(a)-(d)

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) 1.
  - ☐ received in the national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: 1.

### Attachment(s)

- |  |   |
|--|---|
| <input checked="" type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). <u>2</u> | <input type="checkbox"/> Interview Summary, PTO-413                     |
| <input checked="" type="checkbox"/> Notice of Reference(s) Cited, PTO-892                                | <input type="checkbox"/> Notice of Informal Patent Application, PTO-152 |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948                         | <input type="checkbox"/> Other: <u>1</u> .                              |

U.S. Patent Trademark Office

### Office Action Summary

PTO-326 (Rev. 04/18/01)  
S. N. 09/756,411

Copy for ☒ FILE ☐ APPLICANT

Part of Paper No. **03**

Art Unit 1623

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group 1600, Art Unit 1623.

- 5        No claims have been cancelled and no new claims have been added as of the date of this Office action, An Information Disclosure Statement (IDS) has been received as of January 8, 2001 and entered herein.

Claims 1-20 remain in the case.

- 10        Claims 1-17 and 20 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- 15        Claims 1-17 and 20 are directed to compounds the chemical identities of which have not been specified and are therefore claimed far more broadly than is supportable by the instant disclosed exemplifications. In claims 18 and 19 in particular, the ingredient "ddC" has not been shown to be active against any retroviral  
20        infection including HIV in combination with hydroxyurea or a similarly active compound. In claim 17 the enablement of "AZT" as a active ingredient is questionable in view of the disclosures of the Malley et al. patents which specifically exclude the combination of hydroxyurea and AZT as inactive against HIV in quiescent cells in  
25        culture.

Art Unit 1623

combination of hydroxyurea and AZT as inactive against HIV in quiescent cells in culture.

5 In claims 1-8 and 20 are not properly enabled because it has not been demonstrated herein that any single compound, including hydroxyurea, has been administered as an effective treatment for HIV or any other retroviral infection.

10 Claims 1-4, 6-7, 9-14, 16-18 and 20 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15 In claims 1, 9, 11-12 and 20, the term "a compound that depletes ...;" in claim 9 the term "an antiviral nucleoside phosphate compound;" and in claims 11 and 12 the term "a second compound that ... inhibit(s) replication ... ;" are each directed to chemical compounds which have not been chemically identified thereby rendering the instant claims and some claims dependent therefrom both incomplete and lacking in properly defined metes and bounds. Applicant is respectfully requested to provide specific, chemically identified active ingredient(s) in each independent claim.

20 In claims 16 and 17, the terms "2'-F-dd-araA" and "AZT" are improper because said acronyms (and all other acronyms) are not preceded by a complete chemical name of the compound being referred to; e.g. -- 9-(2-fluoro-2, 3-dideoxyarabinofuransyl)adenine (2'-F-dd-araA) --, or  
25 -- 2'-fluoro-2', 3'-dideoxyarabinoadenosine (2'-F-dd-araA) --, or  
-- 3'-deoxy-3'-azidothymidine (AZT) --, or the like.

Art Unit 1623

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise  
5 extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ 2d 2010  
10 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned  
15 with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **9-17 and 19** are rejected under the judicially created  
20 doctrine of obviousness-type double patenting as being unpatentable over claims **12-22** of U.S. Patent No. **6,046,175**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a binary composition which includes two active ingredients generically defined  
25 in a manner which includes the subject matter previously claimed.

Art Unit 1623

Claims 9-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-8 of U.S. Patent No. 6,194,390. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a method of treating HIV in a human host wherein the active ingredients are defined generically in a manner which includes the subject matter of the previously patented claims.

Claims 9-17 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,521,161. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a method of treating HIV in a human host wherein the active ingredients are defined generically in a manner which includes the subject matter of the previously patented claims.

Claims 9-17 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 5,736,527. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to a method of treating HIV in a human host wherein the active ingredients are defined generically in a manner which includes the subject matter of the previously patented claims.

Claims 9-19 of this application conflict with claims noted above in Patent Nos. 5,521,161, 5,736,527, 6,046,175 and 6,194,390.

Art Unit 1623

37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

Claims 1-8 and 20 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. §112 set forth in this Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission(FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone numbers for the FAX machines operated by Group 1600 are (703) 308-4556 and 703-305-3592 .

Serial No. **09/756,411**

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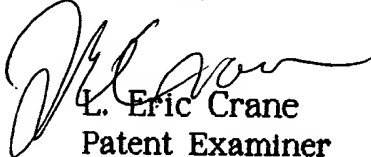
Art Unit 1623

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is 703-**308-4639**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist, can be reached at (703)-308-1701.

10 Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is 703-**308-1235**.

LECrane:lec  
**06/12/01**

  
L. Eric Crane  
Patent Examiner  
Group 1600